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EXAMINER	
LUBIN, VALERIE	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,081	PETERSON ET AL.	
	Examiner	Art Unit	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/05/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *EAST, Proquest search histories*.

DETAILED ACTION

Acknowledgements

1. Claims 1-60 are pending

For reference purposes, the document paper number is 20080807

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-26 and 31 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. The Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. (Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); and Cochrane v. Deener, 94 U.S. 780,787-88 (1876)).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied. This can be done, for example, by identifying the apparatus that accomplishes the method steps, by positively reciting the subject matter that is being transformed, or by identifying the material that is being changed to a different state.

Applicant's method steps in claims 1 and 20 fail the first prong of the new Federal Circuit decision since they are not tied to another statutory class and can be performed without the use of a particular apparatus. Furthermore, the method steps fail to transform underlying subject matter to a different state or thing.

Claims 2-19 and claims 21-26 and 31, as dependents of claims 1 and 20 are rejected under the same analysis.

4. Claims 27-30, and 32-60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

5. Claims 27 and 54 are directed to systems that comprise a computer executable program or software which is not a patentable statutory class.

Claims 28-30, 32-45 and claims 55-60, as dependents of claims 27 and 54, are rejected under the same analysis.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6-13, and 27-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claim 6, the term "drug state data" is unclear. For examining purposes, the claim shall be interpreted as the method of claim1 wherein the method further comprises storing in a memory drug data for at least one subject's drug usage.

Claims 7-13, as dependents of claim 6, are rejected under the same analysis.

9. For claim 7, Applicant states that the memory used to store drug data is remotely located. The claim is indefinite, as it is unclear what the memory is remotely located from, and claims 1 and 6 from which claim 7 depends, are method claims.

Claim 34, containing the same language as claim 7, is rejected under the same analysis.

10. Claims 27 and 54 are directed to systems, yet they recite method steps. Examiner cannot ascertain the metes and bounds of the claim, as it is unclear if Applicant is claiming a system or a method (IPXL Holdings LLC v. Amazon.com Inc., 77 USPQ2d 1140 (CA FC 2005); Ex parte Lyell, 17 USPQ2d 1548 (B.P.A.I. 1990)).

Claims 28-30, 32-45 and claims 55-60, as dependents of claims 27 and 54, are rejected under the same analysis.

11. Claim 31 is indefinite because it recites a system, but depends from claim 26 which is method claim. For examining purposes, the claim shall be considered a dependent of claim 27.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1- 8, 18, 19, are 27-35, 46, 49, 50, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330.

14. With respect to claim 1, Klein discloses a method comprising the steps of selecting a least one drug associated with a predetermined digital patient information (¶ 16, 18); identifying a first start time for administering at least one drug dosage (¶ 17); determining an initial future drug usage from the digital patient information and the first start time (¶32); and identifying a least one subsequent start time and determining a subsequent future drug usage period (¶ 32).

Klein does not specifically recite identifying a least one subsequent start time based on an alteration in the subject's future drug usage; however he does indicate changing dosages and schedules (¶ 10). Therefore, one of ordinary skill in the art would know to change or maintain the schedule for administering a drug based on some change in the drug dosage or the patient's condition in order to better treat such patient.

Furthermore, the last two limitations of claim 1 are repetitions of the second and third limitations, and it has been held that the "mere duplication of parts has no patentable

significance unless a new and unexpected result is produced" (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

Claims 18 and 19 are rejected under the analysis of claim 1.

Claims 27, 52 and 53 are rejected under the analysis of claim 1, as Klein discloses a computer program or software (¶ 28, 31), a memory (¶ 31) and a processor (¶ 28) for performing the steps found in claim 1.

15. Claim 2 is rejected, as Klein recites visually presenting on a computer display the initial future drug usage period (¶ 35, 36).

Claim 3 is rejected under the analysis of claim 2, as it is a mere duplication of claim 2.

Claims 28 and 29 are also rejected under the analysis of claim 2.

16. For claim 4, Klein does not specifically recite the visual presentation of the periods being in the form of a calendar; however, he recites monitoring drug usage using a calendar (¶ 32) and displaying a drug usage period on a computer (¶ 35, 36). A predictable result of Klein would therefore be to display the calendar used to monitor the drug usage period on the computer display (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 5 is rejected under the analysis of claim 4, as the type of calendar displayed is non-functional descriptive material that does not further limit the step of displaying a drug usage period using a calendar (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 30 and 31 are rejected under the analysis of claims 4.

17. Claim 6 is rejected, as Klein discloses storing drug data in a memory (¶ 31).

Claim 7 is rejected under the analysis of claim 6.

Claims 32-34 are rejected under the analysis of claim 6.

18. Claim 8 is also rejected, as Klein recites drug data being accessible by at least one party (¶ 39).

Claim 35 is rejected under the analysis of claim 8.

19. Claim 46 is rejected because Klein recites a personal digital assistant (¶ 28).

20. For claims 49 and 50, Examiner takes Official notice that storing software on a computer executable medium such as a compact disk or a floppy was old and well known in the art at the time the invention was made. Therefore, one of ordinary skill in the art would know to combine the teachings of Klein with the prior art in order to be able to run the program of different microprocessors.

21. Claims 9-17, 36-45, 47, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of Stasny Pre-Grant Pub No. 2003/0074234.

22. With respect to claim 9, Klein recites drug data being accessible by at least one party (¶ 39). Klein does not recite the at least one party offering at least one recommendation based on the drug data, but Stasny does (¶ 4, 5, 50). It would therefore have been obvious to combine the teachings of Klein with those of Stasny in order to allow customers to have access to a variety of products and make better drug selection decisions.

Claim 39 is rejected under the analysis of claim 9.

23. Claim 10 is rejected, as Stasny discloses a pharmaceutical company recommending purchases of pharmaceutical products (¶ 50).

Claim 40 is rejected under the analysis of claim 10.

24. Claim 11 is rendered obvious, as Stasny recites a customer accessing drug data that is tailored for the customer based on the customer's profile (¶ 50).

Claim 12 is rejected under the analysis of claim 11, as the type of characteristics by which the drug data is grouped is non-functional descriptive material that does not further limit the method claim of grouping the drug data (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 36 and 37 are also rejected under the analysis of claim 11.

25. Claim 13 is rejected, as Stasny recites a pharmaceutical company, a health care professional, an insurance company, and a party authorized to access the subject's drug data (Abstract).

Claim 38 is rejected under the analysis of claim 13.

26. Claim 14 is rejected, as Stasny recites educational information about a drug (¶ 45, 50, 53, 60).

Claims 41 and 42 are rejected under the analysis of claim 14.

27. Claim 15 is also rejected, as Klein and Stasny disclose instructions to aid in administering the drug (Klein: ¶ 38; Stasny: ¶ 52, 60).

Claim 43 is rejected under the analysis of claim 15.

28. With respect to claim 16, Klein does not specifically disclose identifying an issue by visually presenting instructions; however, Stasny discloses a customer requesting information (¶ 78, 81) and displaying information about a prescription including directions (¶ 83). Claim 16 is thus rendered obvious over Klein and Stasny, because a predictable result of Stasny would be to request more information on an issue identified in the displayed information (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 44 is rejected under the analysis of claim 16.

29. With regards to claim 17, it is rejected under the analysis of claim 16 because the type of drug to which the method is applied to and the type of issue to be addressed are non-functional descriptive material that do not further limit the method steps found in parent claim 16 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 45 is rejected under the analysis of claim 17.

30. Claims 47 and 48 are rejected, as Stasny recites multimedia presentations including audio, video presentations and hyperlinks to web pages (¶ 60).

31. Claim 51 is rejected, as Stasny discloses using the internet (¶ 46, 47).

32. Claims 20- 22, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of Rottem, U.S. Patent No. 6,769,602.

33. With respect to claim 20, Klein discloses a method comprising the steps of selecting a least one drug associated with a predetermined digital patient information (¶ 16, 18); identifying at least one start time for administering at least one drug dosage (¶ 17); and determining a future drug usage from the digital patient information and the at least one start time (¶32).

Klein does not recite determining a risk period, but Rottem does (Abstract). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Klein and Rottem to determine a risk period based on the patient and the start time of administering a drug in order to better monitor patient's response to the administered drug and to determine following courses of action.

Claim 54 is rejected under the analysis of claim 20.

34. Claim 21 is rendered obvious, as Klein recites visually displaying a drug usage period on a computer display (¶ 35, 36). A predictable result of Klein would be to display any period affected by drug usage such as a risk period (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 55 is rejected under the analysis of claim 21.

35. Claim 22 is rejected, as Klein recites educational information about at drug (¶ 38).

Claim 56 is rejected under the analysis of claim 22.

36. Claims 23-26 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of Rottem, U.S. Patent No. 6,769,602, further in view of Stasny Pre-Grant Pub No. 2003/0074234.

37. With respect to claim 23, Klein and Rottem do not specifically recite educational information including at least a risk associated with a drug, but Stasny does (¶ 52, 83).

Claim 57 is rejected under the analysis of claim 23.

38. Claim 24 is rejected, as Stasny recites side-effects (¶ 52). Furthermore, the type of risk data included in the educational information in non-functional descriptive material that does not further limit the parent claim 23 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 59 is rejected under the analysis of claim 24.

39. With regards to claim 25, it has been held that a "clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim" ((Texas Instruments Inc. v. International Trade Commission 26, USPQ2d 1010 (Fed. Cir. 1993); Griffin v. Bertina, 62 USPQ2d 1431 (Fed. Cir. 2002); Amazon.com Inc. v. Barnesandnoble.com Inc., 57 USPQ2d 1747 (CAFC 2001)). Claim 25 is therefore rejected under the analysis of claim 23.

Claim 58 is rejected under the analysis of claim 25.

40. With regards to claim 26, it is rejected under the analysis of claim 25 because the type of drug to which the method is applied to and the type of risk identified, are non-functional descriptive material that do not further limit the method steps found in parent claim 20, from which claims 23 and 25 depend (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 60 is rejected under the analysis of claim 26.

Conclusion

41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a) Friedman et al. Pre-Grant Pub No. 2004/0142914 and Bratzler et al., Pre-Grant Pub No. 2002/0091097 disclose contraceptives including patches being administered, and risk of pregnancy.

b) Jacobson, U.S. Patent No. 6,488,205 recites storing a computer program on a medium such as a compact disk or diskette.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626